GEORGIA INSTITUTE OF TECHNOLOGY
OFFICE OF CONTRACT ADMINISTRATION
SPONSORED PROJECT INITIATION

Date: 9/22/80

Project Title: INVESTIGATORSHIP AGREEMENT FOR FLUID DYNAMIC STUDIES OF PROSTHETIC HEART VALVES.

Project No: E-19-618

Project Director: DR. A. P. YOGANATHAN misc

Sponsor: AMERICAN HEART ASSOCIATION, GEORGIA AFFILIATE

Agreement Period: From 7/1/80 Until 6/30/83

Type Agreement: GRANT (ACCEPTED BY GTRI 6/4/80)

Amount: $30,000 (PARTIALLY FUNDED FOR $10,000 THRU 6/30/81)

Reports Required: ANNUAL PROGRESS REPORT

Sponsor Contact Person (s):

Technical Matters

Contractual Matters (thru OCA)

MS. ANN ANGELO, PROGRAM DIRECTOR
AMERICAN HEART ASSOCIATION
GEORGIA AFFILIATE
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ATLANTA, GA 30324
(404) 261-2260

Defense Priority Rating: NONE

Assigned to: CHEMICAL ENGINEERING (School/~~Laboratory~~)

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GEORGIA INSTITUTE OF TECHNOLOGY OFFICE OF CONTRACT ADMINISTRATION

SPONSORED PROJECT TERMINATION SHEET

Date August 23, 1983

Project Title: Investigatorship Agreement for Fluid Dynamic Studies of Prosthetic Heart Valves

Project No: E-19-618

Project Director: Dr. A. O. Yoganathan

Sponsor: American Heart Association, Georgia Affiliate

Effective Termination Date: 6/30/83

Clearance of Accounting Charges: 6/30/83

Grant/Contract Closeout Actions Remaining:

- [ ] Final Invoice and Closing Documents
- [ ] Final Fiscal Report
- [x] Final Report of Inventions
- [ ] Govt. Property Inventory & Related Certificate
- [ ] Classified Material Certificate
- [ ] Other __________

Grant was funded in quarterly installments so no final invoice was required.

Assigned to: Chemical Engineering (School/~~Laboratory~~)

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PROGRESS REPORT

The following report outlines briefly the progress made on the project during the time period July 1 to October 12, 1981.

Detailed steady and pulsatile flow pressure drop and regurgitation studies have been conducted on the following valves: Carpentier-Edwards, Ionescu-Shiley and Hancock tissue valves; St. Jude bi-leaflet, Hall-Kaster tilting disc, Omni-Science tilting disc and the 70° Bjork-Shiley tilting disc mechanical valves. At least two sizes of each valve design was studied in both the aortic and mitral positions. When these results are analyzed together with previous results obtained for some of the older mechanical valves, the prostheses could be arranged in the following order of decreasing stenoticity: (i) Kay-Shiley and Beall disc valves; (ii) Starr-Edwards and Smeloff-Cutter ball valves, and Carpentier-Edwards and Hancock porcine valves, (iii) Ionescu- Shiley pericardial valve and 60° Bjork-Shiley tilting disc valves; (iv) 70° Bjork-Shiley and Hall-Kaster tilting disc valves, (v) St. Jude bi-leaflet valve and Omni-Science tilting disc valves. In terms of regurgitation the valves can be arranged in the following order of increasing regurgitation: (i) porcine valves; (ii) Ionescu-Shiley pericardial valve; (iii) Starr-Edwards ball valve, and Kay-Shiley and Beall disc valves; (iv) Smeloff-Cutter ball valve, Bjork-Shiley, Hall-Kaster and Omni-Science tilting disc valves, and St. Jude bi-leaflet valve. The fact that the current tissue valves are much more stenotic compared to the new low profile mechanical valves becomes more and more apparent as the valve size becomes smaller.

Flow visualization, and velocity and shear stress studies have been performed on the tissue valves and the new mechanical prostheses under steady flow conditions. Preliminary pulsatile flow studies have just begun. These studies indicated that all the valves studied create bulk turbulent shear stresses large enough to cause sub-lethal and/or lethal damage to red blood cells and platelets. In the aortic position the valves create wall shear stresses which could cause sub-lethal damage to the wall of the proximal ascending aortia. The tissue valves also created jet type flow which could damage the aortic or ventricular wall, if the jet impinges on these walls. The velocity measurements with the tissue valves also showed a region of flow separation and recirculation near the walls of the flow channel immediately downstream of the valve sewing ring. This region of flow separation in the annular space between the valve leaflets and the walls could lead to the deposition of calcific and thrombotic material on the out-flow surface of the leaflets. In addition, excess fibrous tissue could grow on the sewing ring and up along the base of the out-flow surface of the leaflets.

The new mechanical valves also exhibited regions of flow stagnation and/or flow separation adjacent to their superstructures. Such regions could lead to thrombus formation and/or excess tissue growth on and around the prosthesis and cause valve dysfunction. These regions of flow stagnation and/or separation are, however, smaller than theose observed with the older mechanical designs.

We have constructed models of the various types of pulmonic and aortic valved conduits that are presently commercially available. Detailed fluid dynamic studies are presently in progress. The Carpentier-Edwards, Ionescu-Shiley and St. Jude valves are being used in the conduit models. The results of this study should provide some very interesting information.

In addition, during the summer we studied the fluid dynamic characteristics of: (i) #19 Hancock aortic valve, (ii) #23 Hancock mitral valve and (iii) #27 Bjork-Shiley miteal valve. All three valves were recovered during surgery at Emory University Hospital. Both Hancock valves were severely stenosed by calcification and fibrosis of the leaflets. In both valves the muscle shelf leaflets were extremely stiff. The Bjork-Shiley valve had a massive thrombus on its out-flow surface which restricted its opening angle to about 30°. In addition, the disc did not close properly. All three valves were studied in the pulse duplicator under appropriate physiologic conditions. Both Hancock porcine valves created large pressure gradients, even at low cardiac out-puts of 2.0 - 2.5 l/min. It was further observed that all three leaflets of both valves had diminished motion especially the muscle shelf leaflets. The measured in vitro pressure gradients corresponded very well with the clinical gradients measured during catheterization. The Bjork-Shiley mitral valve due to its reduced disc opening angle created a larger in vitro pressure gradients than a normally functioning Bjork-Shiley valve. The in vitro gradients corresponded well with the in vivo data. Due to improper closing the valve exhibited larger than normal in vitro regurgitation volumes.

AMERICAN HEART ASSOCIATION-GEORGIA AFFILIATE

INVESTIGATORSHIP AWARD (1980-1983)

FIRST YEAR REPORT (7/80-6/81)

I. Investigator: Professor Ajit P. Yoganthan-Georgia Tech

II. Project Reports

Two major projects were initiated during the past year. They were: (i) fluid dynamic studies of prosthetic heart valves (started 7/80) and (ii) fluid dynamics of the pulmonary artery (started 1/81). In addition, a minor project to interface the pulse duplicator system in our laboratory to an on-line microprocessor system for on-line data analysis was sucessfully completed. All three projects are described below. The research work is being conducted in close collaboration with Dr. R. H. Franch (cardiologist) at the Emory University Hospital. We also interact with Dr. R. Guyton (cardiovascular surgeon) at Emory, cardiologists at U.S.C.-Los Angeles County Medical Center, and the cardiovascular surgery group at Cedars-Sinai Medical Center (Los Angeles).

(a) Fluid Dynamic Studies of Prosthetic Heart Valves

Even after 20 years of experience the problems associated with valve prostheses have not been totally eliminated. Some of these important problems, such as thrombus formation, hemolysis, tissue overgrowth and damage to the endothelial lining of the vessel wall adjacent to the valve are directly related to the fluid dynamics associated with the various valves. Detailed *in vitro* fluid dynamic studies of bioprostheses, the newest designs of mechanical heart valves, and valve conduits are being conducted. The *in vitro* laboratory data will be correlated with clinical and pathologic observations. It is hoped that the results of this research will lead to better and longer lasting heart valve prostheses and related cardiovascular products.

A fully operational left and right heart pulse duplicator system had been completed. Physiological pressure and flow wave forms have been obtained. As a left heart pulse duplicator the system contains a aortic valve chamber (with sinuses), and a mitral valve chamber which represents the left atrium and the left ventricle. The pulse duplicator has been interfaced to a Apple II Plus microprocessor for data collection and analysis. With the on-line microprocessor it is not possible to analyze pressure and flow information from the pulse duplicator beat by beat.

Photography studies of the opening and closing characteristics of the Carpentier-Edwards porcine aortic valves (sized #27 & 25) and Ionescu-Shiley pericardial aortical valves (sizes #27 & 25) have been conducted in the pulse duplicator allowing us to photograph the valve at any instant during the heart cycle. A series of slides (6) showing the opening motion of a size #25 Ionescu-Shiley aortic valve is enclosed.

The photography studies indicate very clearly that the leaflets of the two bioprostheses do not open as ideally as the leaflets of the natural aortic valve. For example, a steady flow rate of 417 cm^3/sec (25 liters/min)the #27 Ionescu-Shiley opens to about 67% of its primary orifice area while the #27 Carpentier-Edwards opens to about 61% of its primary orifice area. The #25 Ionescu-Shiley and Carpentier-Edwards valves open to about 74% and 54% of their primary orifice areas, respectively. It is also observed that the leaflets of the #25 Ionescu-Shiley valve open to a larger extent compared to the #27 Carpentier-Edwards valve under steady and pulsatile flow conditions. The results also show that the planimetered areas of valve leaflet opening for the Carpentier-Edwards valves have larger standard deviations compared to the Ionescu-Shiley valves. The reason for this is that the Ionescu-Shiley calf pericardial valves open more symmetrically and more reproducibly than the corresponding size Carpentier-Edwards porcine prostheses. Results of the opening of the valve leaflets under pulsatile flow conditiions indicate that the Ionescu-Shiley valves open to about the same extent as under steady flow conditions. The Carpentier-Edwards valves, however, open to about 25 to 30% less compared to their corresponding steady flow rate valve leaflet openings. It was also observed that both types of tissue valves opened less at lower cardiac outputs (2.5 liters/min) compared to normal cardiac outputs (5.0 liters/min). The opening characteristics of the valve leaflets can be attributed to their anatomical and elastic characteristics, as well as the tanning processes used by their respective manufacturers.

In vitro fluid dynamic studies (pressure drop, regurgitation, velocity and shear stress measurements) have been made on the Hall-Kaster, Omni-Science and modified convexo-concave Bjork-Shiley tilting disc prosthetic valves. The Carpentier-Edwards and Ionescu-Shiley bioprostheses were also studied. The three tilting disc designs had comparable pressure gradient and regurgitation characteristics. The Omni-Science valves had the lowest pressure gradients. The velocity and shear stress characteristics of the three designs were different due to variations in their superstructures and their opening angles.

The velocity profiles across the four valves studied showed improvements in reducting the obstacles to flow and the wall shear stresses. However, all four designs caused elevated wall shear stresses, especially in the major orifice region, which could cause damage to the endothelial lining of the vessel wall adjacent to the valve. The wall shears are definitely lower than those created by the ball and flat disc type valves. Turbulent shear stresses estimated from turbulence intensity measurements indicate turbulent shear stresses on the order of 100 to 200 N/m^2 in the immediate downstream vicinity of all three designs. These turbulent shear stresses are large enough to cause lethal and/or sublethal damage to blood elements, such as red blood cells and platelets. The regions of flow stagnation and flow separation observed adjacent to superstructures of all four valves, could lead to thrombus formation and/or excess tissue overgrowth on and around the valve prostheses.

The pressure drop studies indicated that tissue valves created relatively large pressure drops. These pressure drops were larger than those observed with the corresponding sizes of Bjork-Shiley, Hall-Kaster, and St. Jude prostheses.

Velocity and shear stress measurements made with a laser-Doppler anemometer indicated that the flow that emerged from the leaflets of tissue valves was like a jet and could lead to turbulent shear stress on the order of 1000-3000 $dynes/cm^2$. Such turbulent shear stresses could be harmful to blood components. The jet type flow could also damage the endothelial lining of the wall of the ascending aorta. Tissue valves, however, created relatively low wall shear stresses on the order of 100-600 $dynes/cm^2$.

During the past year we studied the fluid dynamics characteristics of a #25 St. Jude mitral valve and a #19 Hancock porcine aortic valve, both recovered during surgery at Emory University Hospital. The Hancock valve was stenotic causing pressure drops in the range of 65 to 77 mmHg at cardiac outputs of about 5 to 5.5 l/min. These pressure drop results correlated very well with catheterization data on the patient obtained prior to surgery. The St. Jude valve seemed to function normally in the pulse duplicator even though cine-angiography studies had shown the valve to be leaking causing excessive hemolysis in the patient. This was the reason for the subsequent surgery. It was unclear from the angiogram if it was a para-valvular or peri-valvular leak. In the pulse duplicator the valve had a back flow of about 7 to 10% at cardiac outputs ranging from 5 to 2.5 l/min. We are in the process of studying a Bjork-Shiley mitral valve which had thrombus on its downstream face. The adhered thrombus allowed the tilting disc to open only partially thereby causing a significant pressure gradient. In addition, we have visually examined other recovered mechanical and tissue heart valves at Emory University Hospital. These recovered valves have been photographed by Dr. Franch and have been very useful in analyzing locations of thrombus formation and/or tissue overgrowth and encapsulation, and degredation of the valve structure.

Finally, some preliminary experiments were conducted with right heart conduits. In this study we examined the effect of flow through pulmonary conduits with and without a prosthetic valve in the conduit. Initial results seem to indicate, that under certain conditions of pulmonary compliance and resistance it may be possible to use a conduit without a valve and expect reasonable cardiac output through the pulmonary circulation.

(b) Fluid Dynamics of the Pulmonary Artery

The pulmonary circulation differs from the systemic circulation in several important respects. For example, the mean transmural pressure in the large pulmonary arteries in only 15 mmHg as opposed to 100 mmHG in the systemic arteries; the branching pattern is quite different, many more bifurcations being approximately symmetric and most of them occurring after only a few (1.5 to 5) diameters from the parent vessel. A majority of the cardiovascular congenital problems such as tetrology of Fallot, Epstein's anomoly, and absent-pulomanary valve occur on the right side of the heart (i.e., pulmonary circulation). Clinical problems such as pulmonary hypertension and pulmonary artery branched stenosis occur in children and in adults. An understanding, and correction and/or treatment of these congenital and clinical problems requires fundamental knowledge of the hemodynamics of the pulmonary circulation, especially in the pulmonary artery.

The main pulmonary artery branches into two daughter arteries within 1.5 to 5 cm after exiting from the right ventricle. The daughter arteries branch at an angle of about 140^{o} and form an approximate 'Y' shape with the main artery. The geometry of branching of the pulmonary artery is unique in the cardiovascular system. Although *in vitro* studies have been made in the past to study bifurcation geometries of the systemic circulation, no particular attention has been paid to the pulmonary artery. The main objective of this investigation is an *in vitro* fluid dynamic study of the pulmonary artery.

With the help of Dr. R. H. Franch a model of an adult pulmonary artery has been constructed out of Lucite as well as glass. Preliminary steady flow pressure and flow visualization studies have been conducted in the models. Flow visualization studies indicate very complex flow phenomena occurring at the junction of the bifurcation. A series of six photographs are enclosed as examples of the flow visualization work. Steady flow rates of 10 and 25 l/min were used since these flow rates correspond to peak systolic flows through the

the pulmonary artery at cardiac outputs of about 2.5 to 5 l/min. The flow streamlines are straight in the main branch upstream of the junction. As the junction is approached the streamlines near the walls begin to curve towards the respective walls. In the two branches flow separation occurs at the walls near the outer corners of the junction, creating a very complex flow field in the immediate vicinity of the junction. The locations of the flow separation points are approximately the same at both flow rates. It is also possible that a small region of flow stagnation may occur ar the apex of the bifurcation. The preliminary pressure measurements indicate that in certain regions at the junction of the bifurication, artifically low pressures may be measured. These regions correspond to the regions of flow separation observed in the flow visualization studies. Pressure measurements in such regions could lead to false clinical hemodynamic diagnoses, such as stenosis in the main artery and its branches.

(c) On-line Microprocessor

The microprocessor system consists of the following items: (i) Apple II Plus microprocessor (64 K memory), (ii) 2 floppy disc drives (212 K memory), (iii) 8-channel analog-to-digital convertor, (iv) Sanyo 8-inch video screen, (v) DEC Writer IV printer and (vi) appropriate soft-ware. The microprocessor system is interfaced to the pulse duplicator system so that we may perform on-line pressure (p) and volumetric flow (Q) data collection and analysis. We currently can collect two channels of pressure and one channel of flow. The microprocessor system is programmed such that it collects the pressure and flow data on-line, and then provides mean systolic or mean diastolic pressure drop and cardiac output, beat by beat. We can also calculate the mean flow and/or the root mean square of the flow during systole or diastole. In addition, the raw pressure and flow data are stored in a software buffer and can be transferred onto diskette, for long term storage. The stored raw data could be re-analyzed at a later date. These on-line data collection and analysis capabilities have been a tremendous help in our pulsatile flow studies of prosthetic heart valves. It will also be used in our pulmonary artery studies. We are continuously updating the computer software for data collection and analysis. We are currently interfacing the microprocessor system to the laser-Doppler anemometer. A Houston Instruments (DMP-7) multicolor pen plotter is also being added to the microprocessor system so that the processed data may be plotted. Most of the programming for the microprocessor system was done by Dynamic Solutions, Pasadena, CA.

III. (a) Lay Summary

The research work is mainly directed toward understanding the shear and velocity fields in flow past prosthetic heart valves and valved conduits. By knowing the shears and velocities, valves can be designed appropriately to minimize damage to the cellular components of blood and to minimize the opportunity for excess tissue growth on and around the valve prostheses. The shear values are being quantitatively established in the in vitro tests. Work that has been done so far points out the value of this understanding. Using sophisticated laser beam techniques we have evaluated four new designs of tilting disc type heart valves. These valves show an improvement compared to the previous generation of tilting disc valves. Studies performed on tissue bioprostheses indicate that such prostheses have some inherent problems and require further research and development to improve their hemodynamic performance. The overall importance of our research effort is to understand the drawbacks of current prosthetic heart valves, so that better and longer lasting valves may be developed. This in turn would be beneficial to the many patients who suffer from valvular heart disease.

(b) For many years researchers have been studying the flow of blood through the major vessels of the left heart. Unfortunately, little attention has been paid to the major vessels of the right heart. The main reason being that most cardiovascular problems and diseases afflict the left heart and its vessels. However, many congenital cardiovascular problems afflict the right heart and the pulmonary artery. Diseases such as pulmonary hypertension and pulmonary artery branched stenosis also afflict the right side. In order to rectify the congenital problems re-constructive surgery is required. In order to correct the congenital problems and treat some of the hemodynamic diseases of the right heart, a better fundamental understanding of the flow of blood through the pulmonary artery is required. We are therefore studying the fluid dynamics of model pulmonary arteries on the lab bench. The models are made to replicate the human pulmonary artery. The models are made from glass and Lucite. Initial flow visualization and pressure measuremwnt studies in the model arteries indicate very interesting fluid dynamic phenomena. During the coming year we plan to make detailed pressure velocity and shear measurements in the pulmonary models. The results of this study should be of great value to cardiologists and cardiovascular surgeons in treating and correcting right sided cardiovascular problems.

IV. Publications

(a) Abstracts and Presentations

(i) D. M. Stevenson, A. P. Yoganathan and R. H. Franch, The In vitro Fluid Dynamics of the Hall-Kaster and New Bjork-Shiley Heart Valve Prostheses. Presented at the Joint ASME/ASCE Mechanics Conference, Boulder, CO, June 22-24, 1981.

(ii) A. P. Yoganthan, and R. H. Franch, In Vitro Fluid Dynamics of Tissue Bioprostheses. To be presented at the 2nd World Congress in Chemical Engineering, Montreal, Canada, Oct. 4-9, 1981.

(iii) D. M. Stevenson, A. P. Yoganathan and R. H. Franch, Fluid Dynamics of Tilting (Pivoting) Disc Heart Valve Prostheses. To be presented at the 74th Annual AIChE Meeting, New Orleans, LA, Nov. 8-12, 1981.

(iv) A. P. Yoganathan, In Vitro Flow Testing of Prosthetic Heart Valves. To be presented at the Bio-Engineering Symposium, ASME Winter Annual Meeting, Washington, D.C., Nov. 16, 1981.

(v) A. P. Yoganathan, R. H. Franch and E. C. Harrison, Clinical Pathologic Problems Observed with Prosthetic Heart Valves: Possible Relationship to Fluid Dynamics. To be presented at the Bio-Engineering Symposium, ASME Winter Annual Meeting, Washington, D. C., Nov. 16, 1981.

(vi) Organized and chaired a session on "Prosthetic Heart Valve Testing," at the 16th Annual AAMI Meeting, Washington, D. C. May 10-14, 1981.

(b) Manuscripts

(i) D. M. Stevenson, A. P. Yoganathan and R. H. Franch, The Bjork-Shiley Heart Valve Prosthesis: Flow Characteristics of the New 70° Model. Accepted for publication in Scand. J. Thor. Cardiovasc. Surg.

(ii) D. M. Stevenson, A. P. Yoganathan and R. H. Franch, Fluid Dynamics of Tilting (Pivoting) Disc Heart Valve Prostheses. In preparation.

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the pulmonary artery at cardiac outputs of about 2.5 to 5 l/min. The flow streamlines are straight in the main branch upstream of the junction. As the junction is approached the streamlines near the walls begin to curve towards the respective walls. In the two branches flow separation occurs at the walls near the outer corners of the junction, creating a very complex flow field in the immediate vicinity of the junction. The locations of the flow separation points are approximately the same at both flow rates. It is also possible that a small region of flow stagnation may occur ar the apex of the bifurcation. The preliminary pressure measurements indicate that in certain regions at the junction of the bifurication, artifically low pressures may be measured. These regions correspond to the regions of flow separation observed in the flow visualization studies. Pressure measurements in such regions could lead to false clinical hemodynamic diagnoses, such as stenosis in the main artery and its branches.

(c) On-line Microprocessor

The microprocessor system consists of the following items: (i) Apple II Plus microprocessor (64 K memory), (ii) 2 floppy disc drives (212 K memory), (iii) 8-channel analog-to-digital convertor, (iv) Sanyo 8-inch video screen, (v) DEC Writer IV printer and (vi) appropriate soft-ware. The microprocessor system is interfaced to the pulse duplicator system so that we may perform on-line pressure (p) and volumetric flow (Q) data collection and analysis. We currently can collect two channels of pressure and one channel of flow. The microprocessor system is programmed such that it collects the pressure and flow data on-line, and then provides mean systolic or mean diastolic pressure drop and cardiac output, beat by beat. We can also calculate the mean flow and/or the root mean square of the flow during systole or diastole. In addition, the raw pressure and flow data are stored in a software buffer and can be transferred onto diskette, for long term storage. The stored raw data could be re-analyzed at a later date. These on-line data collection and analysis capabilities have been a tremendous help in our pulsatile flow studies of prosthetic heart valves. It will also be used in our pulmonary artery studies. We are continuously updating the computer software for data collection and analysis. We are currently interfacing the microprocessor system to the laser-Doppler anemometer. A Houston Instruments (DMP-7) multicolor pen plotter is also being added to the microprocessor system so that the processed data may be plotted. Most of the programming for the microprocessor system was done by Dynamic Solutions, Pasadena, CA.

III. (a) Lay Summary

The research work is mainly directed toward understanding the shear and velocity fields in flow past prosthetic heart valves and valved conduits. By knowing the shears and velocities, valves can be designed appropriately to minimize damage to the cellular components of blood and to minimize the opportunity for excess tissue growth on and around the valve prostheses. The shear values are being quantitatively established in the in vitro tests. Work that has been done so far points out the value of this understanding. Using sophisticated laser beam techniques we have evaluated four new designs of tilting disc type heart valves. These valves show an improvement compared to the previous generation of tilting disc valves. Studies performed on tissue bioprostheses indicate that such prostheses have some inherent problems and require further research and development to improve their hemodynamic performance. The overall importance of our research effort is to understand the drawbacks of current prosthetic heart valves, so that better and longer lasting valves may be developed. This in turn would be beneficial to the many patients who suffer from valvular heart disease.

(b) For many years researchers have been studying the flow of blood through the major vessels of the left heart. Unfortunately, little attention has been paid to the major vessels of the right heart. The main reason being that most cardiovascular problems and diseases afflict the left heart and its vessels. However, many congenital cardiovascular problems afflict the right heart and the pulmonary artery. Diseases such as pulmonary hypertension and pulmonary artery branched stenosis also afflict the right side. In order to rectify the congenital problems re-constructive surgery is required. In order to correct the congenital problems and treat some of the hemodynamic diseases of the right heart, a better fundamental understanding of the flow of blood through the pulmonary artery is required. We are therefore studying the fluid dynamics of model pulmonary arteries on the lab bench. The models are made to replicate the human pulmonary artery. The models are made from glass and Lucite. Initial flow visualization and pressure measuremwnt studies in the model arteries indicate very interesting fluid dynamic phenomena. During the coming year we plan to make detailed pressure velocity and shear measurements in the pulmonary models. The results of this study should be of great value to cardiologists and cardiovascular surgeons in treating and correcting right sided cardiovascular problems.

IV. Publications

(a) Abstracts and Presentations

(i) D. M. Stevenson, A. P. Yoganathan and R. H. Franch, The In vitro Fluid Dynamics of the Hall-Kaster and New Bjork-Shiley Heart Valve Prostheses. Presented at the Joint ASME/ASCE Mechanics Conference, Boulder, CO, June 22-24, 1981.

(ii) A. P. Yoganthan, and R. H. Franch, In Vitro Fluid Dynamics of Tissue Bioprostheses. To be presented at the 2nd World Congress in Chemical Engineering, Montreal, Canada, Oct. 4-9, 1981.

(iii) D. M. Stevenson, A. P. Yoganathan and R. H. Franch, Fluid Dynamics of Tilting (Pivoting) Disc Heart Valve Prostheses. To be presented at the 74th Annual AIChE Meeting, New Orleans, LA, Nov. 8-12, 1981.

(iv) A. P. Yoganathan, In Vitro Flow Testing of Prosthetic Heart Valves. To be presented at the Bio-Engineering Symposium, ASME Winter Annual Meeting, Washington, D.C., Nov. 16, 1981.

(v) A. P. Yoganathan, R. H. Franch and E. C. Harrison, Clinical Pathologic Problems Observed with Prosthetic Heart Valves: Possible Relationship to Fluid Dynamics. To be presented at the Bio-Engineering Symposium, ASME Winter Annual Meeting, Washington, D. C., Nov. 16, 1981.

(vi) Organized and chaired a session on "Prosthetic Heart Valve Testing," at the 16th Annual AAMI Meeting, Washington, D. C. May 10-14, 1981.

(b) Manuscripts

(i) D. M. Stevenson, A. P. Yoganathan and R. H. Franch, The Bjork-Shiley Heart Valve Prosthesis: Flow Characteristics of the New 70° Model. Accepted for publication in Scand. J. Thor. Cardiovasc. Surg.

(ii) D. M. Stevenson, A. P. Yoganathan and R. H. Franch, Fluid Dynamics of Tilting (Pivoting) Disc Heart Valve Prostheses. In preparation.

AMERICAN HEART ASSOCIATION - GEORGIA AFFILIATE

INVESTIGATORSHIP AWARD (1980-83)

THIRD YEAR REPORT (7/82 - 6/83)

I. Investigator: Professor Ajit P. Yoganathan
Georgia Institute of Technology

II. Project Reports

The three major projects initiated during the first two years of the investigatorship award were continued during the past year. A fourth project on the sound analysis of prosthetic heart valves was started as a collaborative research effort with the Department of Chemical Engineering of the California Institute of Technology. The research work was conducted in close collaboration with Dr. R. H. Franch, cardiologist at Emory University Hospital, Dr. E. C. Harrison, cardiologist at Los Angeles County-USC Medical Center, and Dr. A. Chaux, cardiovascular surgeon at Cedars-Sinai Medical Center (Los Angeles). We also interacted with the Bureau of Medical Devices of the Food and Drug Administration.

(a) Even after 20 years of experience the problems associated with valve prostheses have not been totally eliminated. Some of these important problems, such as thrombus formation, hemolysis, tissue overgrowth and damage to the endothelial lining of the vessel wall adjacent to the valve are directly related to the fluid dynamics associated with the various valves. Detailed *in vitro* fluid dynamic studies of bioprostheses, the newest designs of mechanical and polymeric heart valves, and valve conduits are being conducted. The *in vitro* laboratory data will be correlated with clinical and pathologic observations. It is hoped that the results of this research will lead to better and longer lasting heart valve prostheses and related cardiovascular products.

The major portion of the project effort during the past year was spent in conducting detailed pulsatile flow velocity and shear stress measurements with various valve designs, in both aortic and mitral flow chambers. Such measurements are virtually non-existent in the literature, and are extremely important if we are to understand the fundamental fluid dynamic (hemodynamic) characteristics of prosthetic heart valves. The following size 27 mm valves were studied: Starr-Edwards (1260) ball valve, Bjork-Shiley (CC-C) tilting disc valve, Medtronic-Hall tilting disc valve, St. Jude bi-leaflet valve, Beall (106) disc valve, Ionescu-Shiley pericardial valve, and Hancock (standard and modified orifice) porcine valves. All studies were conducted under physiologic conditions in the Georgia Tech pulse duplicator system, at cardiac outputs of 5 to 6 l/min, using a three beam (two dimensional) laser Doppler anemometer system. Examples of some of the results obtained are given below in brief format:

Previous experience has shown that the flow fields and the shear stress fields near the valves provide the most valuable information. Therefore, half profiles were taken as close as possible to the valve superstructure, and full profiles were obtained a little further downstream. Due to the nature of the 3 beam system, the measurements could not be made as close as those made using a 2 beam system. Therefore, the downstream location where the profiles were taken were different from valve to valve. For some valves, such as the Starr-Edwards and Ionescu-Shiley, the velocity and sheer stress profiles were taken relatively far away from the valve sewing ring, because of the high profiles of these prostheses. Measurements were made at locations where the flow field was thought to be most turbulent or where regions of flow separation and/or stagnation were expected. The highest measured root mean square fluctuating component of the axial velocity (rms) is also provided in the text for each valve. For valves which produced a sharp jet type flow, such as the Ionescu-Shiley, the turbulent shear stress also had a steep rise within a very short radial distance. Hence, the highest turbulent shear stress measured could be lower than the highest turbulent shear stress actually existing in the flow channel. The wall shear stress was also strongly dependent upon the location where the measurements were made. Wall shear stresses higher than the measured values could have existed at certain locations where measurements were not made. However, measurements were made at locations where the wall shear stresses were thought to be the highest. The wall shear stresses for the mechanical valves were calculated based on the viscosity of the water-glycerine (blood analog) solution (3.5 cp). For the tissue valves, experiments were conducted in saline solution. However, the wall shear stresses were also calculated based on a viscosity of 3.5 cp.

(i) Starr-Edwards Aortic Caged Ball Valve

The forward flow formed a circumferential jet along the wall of the flow channel. The flow in the annular region was jet like. A large wake was observed distal to the ball, which was a result of flow separation from the surface of the ball. The closest downstream measurement was taken 26 mm downstream of the sewing ring, since the valve cage itself extended 20 mm downstream of the sewing ring. The highest velocity occurred 30 mm downstream of the valve, which had the value of 183.2 cm/s. The highest shear stress observed was 1861 dynes/cm^2, 30 mm downstream of the valve. The rms value at this point was 65 cm/s, which was also the highest rms value observed. Back scatter measurements in the annular region under steady flow conditions at a flow rate of 25 l/min, indicated that the highest turbulent shear stress was 2900 dynes/cm^2. Therefore, the highest turbulent shear stress in this region under pulsatile flow conditions would be expected to be in the range of 3000-5000 dynes/cm^2. The turbulent shear stress was elevated on the centerline throughout the entire cycle in the whole flow channel. The average value was about 700 dynes/cm^2. Off centerline, it was even more elevated with an average value of 900 dynes/cm^2. The velocity profiles showed that the flow field at peak systole and during the deceleration phase did not change much from 26 to 30 mm downstream of the valve. The flow in the acceleration phase was more evenly distributed at 30 mm than that at 26 mm downstream of the valve. Reverse flow was observed in the central part of the flow channel on the centerline at peak systole and during the deceleration phase. The highest negative velocity was -22.1 cm/s. No reverse flow was observed during the acceleration phase. A region of stagnation about 5 mm in diameter would be expected distal to the cage apex. The off centerline (6.25 mm above centerline) profiles showed a stagnation region in the central part of the flow channel during the deceleration phase. No reverse velocity was measured, which means that the wake had a radius of less than 6.25 mm.

The highest (estimated) wall shear stress measured was 1940 dynes/cm^2, 22 mm downstream of the valve. The measurement upstream of the valve 60 ms after the end of the systole showed the closure back flow of the valve. The leakage back flow of this valve was negligible.

(ii) Bjork-Shiley Aortic Tilting Disc Valve

The flow field produced by this valve was not symmetric. Two high velocity jets were observed, one from the major orifice, and the other from the minor orifice. A low velocity region (relatively stagnant), about 5 mm in width, existed between the major and minor orifice jets at all three cardiac cycle times at which velocity measurements were made. The major orifice jet was wider than the minor orifice jet. The highest velocity and turbulent shear stresses measured in the major and minor orifices were about the same, 210 cm/s, and 1800 dynes/cm^2, respectively. Regions of flow separation could be observed in the major and minor orifices, and the region of flow separation in the minor orifice was larger than that in the major orifice. The largest region of separation was observed 11 mm downstream of the valve in the minor orifice region with reverse velocities extending 7 mm from the wall. Narrow high velocity jets were observed in the minor orifice, beneath the occluder, and adjacent to the flow channel walls. Regions of flow separation (or stagnation) existed next to these jets. The highest shear stress observed was 3363 dynes/cm^2, 7 mm downstream of the valve, on the centerline. This was in the region between the major and minor orifice jets. The obstruction of the occluder was the reason for this elevated turbulent shear stress. The average turbulent shear stress over this region at peak systole was about 1600 dynes/cm^2. The turbulence decayed very rapidly in the major orifice, as the flow travelled downstream. In the minor orifice, the turbulent shear stress did not seem to change, especially at peak systole and during the deceleration phase. The high turbulent shear stress region was more spread out and also tended to persist longer in the minor orifice than in the major orifice. This indicated that the flow was more disturbed in the minor orifice region.

The highest rms value measured was 68.1 cm/s, at the same location that the highest shear stress was measured. The highest leakage back flow was observed next to the flow channel wall, directly upstream from the space between the occluder and the orifice ring, with a negative velocity as high as -22 cm/s, which caused an elevated shear stress of 430 dynes/cm^2.

The highest (estimated) wall shear stress measured was 1380 dynes/cm^2, 26 mm downstream of the valve in the major orifice, roughly the position where the major orifice jet hit the wall.

(iii) St. Jude Aortic Bileaflet Valve

The major part of the forward flow emerged from the side orifices of the valve. The highest velocity measured in the side orifice was 218 cm/s, while in the center orifice it was 223 cm/s. The highest turbulent shear stress in the side orifice was 1780 dynes/cm^2 and the rms value at this location was also the highest, with a value of 52 cm/s. The high turbulent shear stress could be related to the asynchronous opening of the valve leaflets. The highest turbulent shear stress in the center orifice was 1700 dynes/cm^2, with an rms value of 53 cm/s. The 90 degree rotated profile at peak systole showed an average shear stress over the entire flow channel of about 1200 dynes/cm^2. The velocity profiles showed two dips due to the presence of the leaflets, which also led to high turbulent shear stresses. The region of forward flow narrowed down as the flow travelled downstream. Flow separated from the orifice and sewing rings of the valve. The region of reversed flow along the centerline, grew from 3 mm from the wall 8 mm downstream of the valve, to 5 mm from the wall 13 mm downstream of the valve, during the deceleration phase. The region of flow separation, 6.25 mm above the centerline, was larger than that on the centerline. The highest reverse velocity measured in the region of separation was -28 cm/s. Leakage back flow was measured upstream of the central pivot of the valve during diastole with a negative velocity of -16 cm/s (highest value), and a turbulent shear stress of 325 dynes/cm^2. The highest estimated wall shear stress was 630 dynes/cm^2.

(iv) Hancock Modified Orifice Aortic Porcine Xenograft

This valve also produced a high velocity jet. The velocity profiles showed that the jet was relatively symmetric 10 mm downstream of the valve, and not as symmetric 15 mm downstream of the valve. This indicated that the fluid did not flow axially. The velocity profiles showed a dip in the center of the jet. The highest velocity and turbulent shear stress measured were 335 cm/s and 3075 dynes/cm^2, respectively, 10 mm downstream of the valve. The off centerline profiles showed no significant change in the velocity and turbulent shear stress from the centerline profiles, at peak systole. The high turbulent shear stresses were confined to a narrow region around the jet. The peak velocity of the jet decreased to 180 cm/s as it moved from 10 to 15 mm downstream of the valve. Although the peak turbulent shear stress also decreased to 2450 dynes/cm^2, the turbulence did not decay very rapidly. Flow separated from the downstream edge of the leaflets. The region between the jet and the wall was relatively stagnant, and no high velocity reversed flow was measured. This implied that the region between the outflow surfaces of the leaflets and the wall was stagnant. The highest rms value measured was 74 cm/s. The highest estimated wall shear stress was 490 dynes/cm^2, 63 mm downstream of the valve. No leakage back flow was observed.

(v) Beall Mitral Caged Disc Valve

This valve produced a circumferential jet, which narrowed down as it travelled from 11 to 17 mm downstream of the valve. The closest profile was taken 11 mm downstream of the valve, which was 3 mm downstream of the fully opened occluder. The velocity of the jet increased as the jet narrowed. The highest velocity measured was 113 cm/s, 17 mm downstream of the valve. The highest shear stress measured was 1926 dynes/cm^2, also 11 mm downstream of the valve. The rms value at this measuring point was 65 cm/s, which was also the highest rms value measured. Only very narrow regions of high turbulent shear stress existed on the edge of the jet. The turbulent shear stress decayed very rapidly from 11 to 17 mm downstream of the valve. The high turbulent shear stress was only 688 dynes/cm^2, 17 mm downstream of the valve. A large wake existed downstream of the occluder, which was the result of boundary layer separation from the edge of the occluder. A high negative velocity was measured in the wake at peak diastole and during the deceleration phase. During the acceleration phase, this region was relatively stagnant. The highest negative velocity was -31 cm/s, during the deceleration phase, 17 mm downstream of the valve. The turbulent shear stresses and rms values in the wake region were almost zero. The highest estimated wall shear stress was 1780 dynes/cm^2, 25 mm downstream of the valve. The leakage back flow of this valve was negligible.

(vi) Medtronic-Hall Mitral Tilting Disc Valve

These results were very different from those obtained in the aortic position. Most of the forward flow emerged from the major orifice of the valve. The highest turbulent shear stress measured in the major orifice was 2591 dynes/cm^2, 18 mm downstream of the valve. The occluder was oscillating during diastole, which could have led to the shedding of vortices downstream and caused high turbulent shear stresses. This phenomena was not observed in the aortic position. The highest velocity was 105 cm/s, at the same downstream location in the major orifice. The highest velocity in the minor orifice occurred beneath the occluder, 18 mm downstream of the valve, and was 97 cm/s. The forward flow was confined in a very narrow region in the minor orifice. The highest turbulent shear stress in the minor orifice was 1800 dynes/cm^2, 8 mm downstream of the valve. The highest rms values were 54 cm/s and 45 cm/s, in the major and minor orifices, respectively. The largest region of flow separation existed in the minor orifice, which extended 18 mm from the wall. Flow separation in the major orifice existed only at peak diastole, and extended only 5 mm from the wall. The profile downstream of the 90 degree rotated valve showed that the flow separated from the stent in the minor orifice. The highest (estimated) wall shear stress measured was 480 dynes/cm^2, 59 mm downstream of the valve. The upstream velocity profiles showed that the back flow occurred in the center of the flow channel, through the hole in the occluder. The highest turbulent shear stress measured at this location was 713 dynes/cm^2.

(vii) St. Jude Miral Bileaflet Valve

The velocity profiles had three peaks; one from the center orifice, and two from the side orifices. The highest velocity was 103 cm/s in the side orifices. The highest turbulent shear stress, in the side orifices, was 574 dynes/cm2, 19 mm downstream of the valve, and 10 mm above centerline. The rms value at this point was 28 cm/s. The highest turbulent shear stress in the center orifice was 760 dynes/cm2. Flow separated from either side of the orifice and the sewing ring of the valve. The largest region of flow separation existed 12 mm downstream of the valve, in the center orifice, which extended 15 mm from the wall. The two leaflets of the valve did not open at the same time. The effect was not obvious on the centerline of the flow channel, but from the off-centerline velocity profile during the acceleration phase, this phenomenon was clearly observed. The highest (estimated) wall shear stress measured was 200 dynes/cm^2, 50 mm downstream of the valve. During systole, back flow existed in the center part of the flow channel, with a reverse velocity as high as -17 cm/s, which led to a turbulent shear stress of 117 dynes/cm^2.

(viii) Hancock (Std) Mitral Porcine Xenograft

This valve produced a high velocity jet. The jet was confined to a narrow region which was not in the center of the flow channel, but a little bit shifted to one side. The highest velocity measured was 216 cm/s, 17 mm downstream of the valve. The highest shear stress measured was 1947 dynes/cm^2, and the highest rms value was 62 cm/s, 10 mm downstream of the valve, and 10 mm below the center line. The high turbulent shear stresses were confined to a narrow region around the jet. The measurements showed that the flow field did not change much from 10 to 17 mm downstream of the valve. The peak velocity decreased to 165 cm/s when measured 10 mm below the centerline. The jet narrowed, and a dip showed up in the central part of the velocity profile, which caused high turbulent shear stresses. Flow separated from the downstream edge of the leaflets. The region around the jet appeared to be relatively stagnant; no high velocity reverse flow was measured. This implied the region behind the leaflets was stagnant. The highest (estimated) wall shear stress measured was 260 dynes/cm^2, 63 mm downstream of the valve.

(ix) Ionescu-Shiley Mitral Pericardial Xenograft

A high velocity jet was produced by this valve, which occupied a narrow region in the central part of the flow channel. The velocity profiles during the acceleration phase showed a dip in the center, which still could be seen at peak diastole. The jet had about the same velocity 21 and 27 mm downstream of the valve. The highest velocity measured was 191 cm/s, 27 mm downstream of the valve. The highest shear stress measured was 1376 dynes/cm^2, and the highest rms value was 46 cm/s, 27 mm downstream of the sewing ring. The high turbulent shear stresses were confined to a narrow region around the jet. Flow separated from the downstream edge of the leaflets. The region around the jet was stagnant, and extended about 17 mm from the wall. This implied the region behind the leaflets was stagnant. The highest estimated wall shear stress measured was 320 dynes/cm^2. The measurement upstream of the valve during diastole, showed that the back flow occurred in the center of the flow channel, which was caused by the closing movement of the valve leaflets.

The turbulent shear stresses measured downstream of all the valve designs studied are large enough to cause sub-leathal and/or leathal damage to red-cells and platelets. Wall shear stresses larger than 400 to 600 dynes/cm^2 could cause damage to the endothelial tissue of the vessel or chamber walls. Furthermore, the regions of flow stagnation and flow separation observed adjacent to the various valve designs, correlate well with locations of thrombus formation and excess tissue overgrowth observed on recovered valves of the same designs.

During the year we also examined and studied Beall, Starr-Edwards, Kay-Shiley, Bjork-Shiley, St. Jude and Porcine heart valves, recovered at surgery and/or autopsy. Pathologic studies of the mechanical and tissue valves showed that the locations of thrombus formation and excess fibrotic tissue growth correlated well with the <u>in vitro</u> flow patterns of the various valve designs. The recovered valves were also studied in the Georgia Tech pulse duplicator under appropriate physiologic conditions to evaluate their fluid dynamic (hemodynamic) characteristics. The obtained <u>in vitro</u> results correlated quite well with the available clinical information and data. An interesting example of one of the studies conducted is given below:

Three Beall valves with Teflon discs recovered from patients undergoing surgery at Emory University Hospital, were evaluated for their regurgitation characteristics on the Georgia Tech pulse duplicator system.

All three discs had varying degrees of notching and wear marks. In one case the disc had been notched and worn to such an extent that it had escaped from the valve cage. The disc was, however, recovered from the patient's descending thoracic aorta. All three valves were tested in the mitral position under the following conditions: (i) heart rate of 70 min, (ii) systolic time of 300 ms, (iii) mean aortic pressure of 90 - 100 mm Hg, and (iv) cardiac output in the range of 2.0 to 7.5 l/min. In addition, the opening and closing motions of the discs were observed and photographed with a SLR camera. In the case of the valve with the escaped disc, a high-speed (200 frames/sec) 16 mm movie was made of the disc motion.

Due to the notching and wear marks on their respective discs, all three valves were excessively regurgitant as shown by the results in Table 1. In addition, the discs showed improper and unpredictable movement within their valve cages. Under certain conditions the Teflon discs cocked both in the open and/or closed positions. The cocking of the discs in the closed positions led to severe regurgitation. All three valves were removed at surgery, due to clinical manifestations of varying degrees of regurgitation. The improper disc motions are shown very clearly in the 16 mm high speed movie film. In this particular case, the opening characteristics depict the disc in a "floating" type motion. The film also clearly shows the disc opening and closing in cocked positions, and the variations in the opening and closing motions from cycle to cycle.

Table 1: Regurgitant Volumes for the Beall Valves

Valve #	Cardiac Output l/min	Total Regurgitant Volume* ml/beat
1	7.4	16.2
1	5.3	14.1 - 43.1
1	2.1	36.4
2+	5.5	51.0
2+	3.8	35.3
2+	2.0	45.7
3	8.2	22.3
3	5.1	37.6
3	4.0	59.1
3	3.5	47.0

* closure plus leakage volumes

\+ valve with escaped disc

(b) Fluid Dynamics of the Pulmonary Artery

The pulmonary circulation differs from the systemic circulation in several important respects. For example, the mean transmural pressure in the large pulmonary arteries is only 15 mm Hg as opposed to 100 mm Hg in the systemic arteries; the branching pattern is quite different, many more bifurcations being approximately symmetric and most of them occurring after only a few (1.5 to 5) diameters from the parent vessel. A majority of the cardiovascular congenital problems such as tetrology of Fallot, pulmonic stenosis, and absent-pulmonary valve occur on the right side of the heart (i.e., pulmonary circulation). Clinical problems such as pulmonary hypertension and pulmonary artery branched stenosis occur in children and in adults. An understanding, and correction and/or treatment of these congenital and clinical problems requires fundamental knowledge of the hemodynamics of the pulmonary circulation, <u>especially</u> in the pulmonary artery.

After preliminary flow visualization studies conducted during the second year of the investigatorship award, it was realized that the pulmonary artery models being used were not an accurate representation of the human pulmonary artery. The problem was associated with the proper location of the branch point to the left and right pulmonary arteries. After studying many right heart angiograms and pulmonary arteries obtained during autopsy, we now feel we have models that closely approximate the human pulmonary artery and its two main branches.

Detailed steady and pulsatile flow visualization studies have been conducted in the adult size pulmonary artery model. The studies were conducted for situations which mimic normal, mildly stenotic and severely stenotic pulmonic valves. In addition, preliminary steady flow velocity measurements have been conducted for the above three cases with a 3-beam (2-dimensional) laser-Doppler anemometer system. The above studies clearly show the fluid dynamic (hemodynamic) characteristics of the jet created by varying degrees of pulmonic stenosis. The severely stenosed pulmonic valve creates velocities on the order of 4 to 6 m/s and very high levels of turbulent fluctuations. These turbulent fluctuations are quite capable of causing post stenotic dilatation, as observed clinically in patients with pulmonic stenosis. The *in vitro* velocity measurements also clearly show that the jet created by the stenotic valve is directed towards the left branch, thereby leading to quite different flow fields in the left and right branches. The velocities measured *in vitro* compare quite well with recent measurements made with Doppler ultrasound in patients, by Dr. David Sahn and his colleagues at the University of Arizona Medical Center. We are presently in the process of trying to establish a collaborative research effort with Dr. Sahn. A summary of the flow visualization studies is given below:

The steady flow visualizations were conducted, varying the flowrate over a range of 10 - 30 liters/min and the split of the volumetric flow through the two branches. In general, it was observed that the fluid exited from the valve as a central jet. This jet broadened progressively as it traveled down the main pulmonary artery by entraining the surrounding fluid until it reached the origin of the two branches. The jet then narrowed, bypassed the origin of the two branches and hit the distal end of the pulmonary artery. The jet subsequently broke up into two smaller jets which flowed along the distal walls of their respective branches. The sizes of these two jets depended greatly on the location of the junction of the two branches. For example, when the junction of the two branches was located directly opposite the valve, the majority of the central jet went into the right pulmonary artery. This flow pattern only has been clinically observed in the presence of the congenital disease, the transposition of the great vessels. However, when the junction of the two branches was located directly above the right wall of the main pulmonary artery the central jet almost completely bypassed the right branch and went into the left branch. This caused the size of the jet going into the right branch to be very small. This flow behavior has been clinically observed in patients with pulmonic stenosis.

Furthermore, it was observed that the flow fields in the two arms were disturbed producing regions of secondary flow. The dimensions of these regions of secondary flow have been measured from selected photographs. These values led to the conclusion that the amount of the disturbance in the arms depended on the specific geometry of the model. For example, in the model with the junction located above the valve, the flow field recovered at a distance further down the right branch than the left. This seemed to indicate that the jet in the right arm was more intense. The opposite indication was found in the model with the junction located above the right wall of the main pulmonary artery. In fact, in the right branch, the flow field recovered within an extremely short distance down this branch, indicating that the jet in the left branch was very intense. Another possible factor affecting the flow field was the amount of curvature designed into the left branch. In the human body, the left pulmonary artery within a short distance curves back toward the spinal cord over the air tract and goes to the left lung, after branching from the main pulmonary artery. This factor was designed into some of the models to see the affect, but no major qualitative differences were observed between the types of models with and without the curvature in the left branch. For example, the distance down the left branch at which the flow field recovered was approximately equal to the distance for the flow field in the model without the curvature.

The size and position of the regions of secondary flow depended on the specific geometry of the model and the split of volumetric flow through the two branches. The size of these regions, also, depended on the size of the models, but in general, the locations of these regions were not affected by size. In the model with the junction positioned above the valve, regions of secondary flow were visible at the origins of the two branches and at the walls of the main pulmonary artery behind the valve. In the model with the junction above the right wall of the main pulmonary artery, the areas of secondary flow were visible in the same locations as previously described, but the size of the area of secondary flow in the right branch origin greatly decreased while the size of the region in the left branch increased. In these regions, it was observed that the particles seemed to travel down the wall in the pattern of a helix, which was probably caused by the particles hitting the wall and traveling towards the jet and then being pushed back towards the wall by the jet.

The pulsatile flow visualization studies were conducted at a 50/50 split of flow through the two branches and at a cardiac output of 4 - 5 liters/min. Pictures were taken at different times during the cardiac cycle, at a heart rate of 70 beats/min, and a mean pulmonic pressure of 20 mm Hg. It was observed that at the beginning of the flow, there were no visible areas of secondary flow. Then as the flow increased, the secondary flow regions became visible and the flow patterns began to resemble those seen in steady flow visualization, until peak flow was reached. Then the flow began to decrease causing the intensity of the jet to decrease. This caused the regions of secondary flow to increase until there was no flow in the system and the valve closed.

The above study only considered a normal to mildly stenotic pulmonary valve. Further work is currently in progress in analyzing the flow fields downstream from mild to severely stenotic pulmonary valves, under steady and pulsatile conditions.

Steady flow pressure measurements made in the pulmonary models indicate quite clearly that the pressure fields within the pulmonary artery and its two main branches can vary significantly from location to location. Therefore, catheterization measurements in the right heart should be interpreted appropriately.

(c) Computer Modeling of Flow Through Trileaflet Heart Valve Prostheses

The replacement of diseased valves is now widely practiced, and has consequently increased the interest in understanding fundamentally how the artificial valve design affects the flow of blood across it. Computational fluid dynamics has been applied to this problem to provide relatively fast and cheap evaluation of the fluid dynamic characteristics of the valve. Unfortunately, none of the models currently published have accounted for the presence of turbulence, which has been documented for prosthetic aortic valves both _in vitro_ and _in vivo_. Consequently, a two-equation turbulence model devloped by Gosman has been applied to the steady flow case of blood flow across an axisymmetric trileaflet valve. A trileaflet valve was chosen because it is a valve design in current widespread clinical use (i.e.: tissue bioprostheses). In addition, its geometry approximates that of the natural trileaflet valves. A brief summary of the results obtained to date is given below.

The time-averaged Navier-Stokes equations were coupled with the K-ε turbulence model to produce a simulation of steady blood flow through a porcine tissue valve. An axisymmetric assumption was made to maintain computational time at a reasonable level. A grid generation program was interfaced with the simulation program to simplify the no-slip boundary condition specification. The grid follows the ventricular wall, both sides of the leaflet, and finally the aortic wall. The resulting velocity profiles follow experimental data very well in regions where the turbulent boundary layer does not exist. In regions where this boundary layer does exist, the model tends to underpredict the velocity gradient at the wall. The flow through the valve is jet like with a maximum velocity of 400 cm/sec. at a flow rate of 30 liter/min. The predicted turbulence shear stresses compare very well with in vitro experimenal observations. The peak turbulence shear stress at 0.8 diameters downstream was 1300 dyne/cm^2, compared to an experimental value of 1800 dyne/cm^2 at 0.83 diameters downstream.

(d) A Quantitative Method for the In Vitro Study of Sounds Produced by Prosthetic Heart Valves

A method was developed for analyzing sounds produced in vitro by prosthetic aortic heart valves, together with a one-dimensional harmonic model. Procedures for estimating physical parameters of the model are outlined for the case of transient and non-transient sounds, and a computational method is described for making comparisons between two general sounds. The Fast Fourier Transform provides a satisfactory means for the basic transformation to the frequency domain. Useful representations of the acoustical information that are considered are the original time and amplitude plots, pwoer-density spectra, power-distribution functions, a 3-D (three-dimensional) surface of power-frequency-time, sections of these 3-D surfaces, and a 3-D, power-distribution surface showing the difference between two 3-D, power-distribution surfaces. Note is made that each reprsentation is useful for indicating specific acoustical characteristics which may be important when either comparing or describing sounds. The spectra provide an accurate means for estimating the parameters of the model and provide clearer comparisons when compared to the time-amplitude plots. This fact is most clearly shown by the 3-D, power-difference surface. This surface provides a very convenient means for the overall comparison of two sounds. An example of the application of the above method is summarized below.

A comparative study was made of the sounds produced by a normal, Starr-Edwards 2400, aortic valve prosthesis with those produced by the same valve but having a simulated overgrowth at the apex of the struts. Comparisons were made over the entire cardiac cycle for (1) time and amplitude, (2) power-density spectra, (3) power-distribution spectra, (4) power-distribution surfaces associated with individual valves, and (5) a 3D, power-distribution-difference surface. Power-density spectra were compared for portions of the cycle corresponding to the opening, systolic, and closing sounds of the valve. Physical parameters of an acoustical model were estimated from the power-density spectra. The results showed that each comparison gave information pertinent to the simulated malfunction. Opening, systolic, and closing sounds, respectively, were different for each valve. The opening sound of the abnormal valve displayed a much lower frequency. Systolic sounds for the two valves were similar in frequency, but the normal valve produced more total power for this sound. The closing sound of the abnormal valve occurred later than that of the normal valve. These differences were more clearly seen when viewed in the frequency domain.

III. Lay Summary

(a) The research is mainly directed toward understanding the fluid dynamic performances of different designs of prosthetic heart valves. In order to evaluate the performances pressure drop, regurgitation, and velocity and shear stress measurements are being conducted in a flow system which duplicates the pulsating flow of the heart. Using sophisticated laser beam techniques, velocity and shear fields are measured in the immediate vicinity of the valves. By knowing the shear and velocity fields, valves can be appropriately designed to minimize damage to the cellular components of blood and to minimize the opportunity for excess tissue growth on and around valve prostheses. The pressure gradient and regurgitant characteristics are two of the major determinants in the clinical use of a given valve design. The overall importance of our research efforts is to understand the advantages and disadvantages of current prosthetic heart valves, so that better and longer lasting valves may be developed. This in turn would be beneficial to the many patients who suffer from valvular heart disease.

(b) For many years researchers have been studying the flow of blood through the major vessels of the left heart. Unfortunately, little attention has been paid to the major vessels of the right heart. The main reason being that most cardiovascular problems and diseases afflict the left heart and its vessels. However, many congenital cardiovascular problems afflict the right heart, the pulmonary artery and the pulmonic valve. Diseases such as pulmonary hypertension and pulmonary artery branched stenosis also afflict the right side. In order to rectify the congenital problems reconstructive surgery is required. Therefore, to correct the congenital problems and treat some of the hemodynamic diseases of the right heart, a better fundamental understanding of the flow of blood through the pulmonary artery is required. We are therefore studying the fluid dynamics of model pulmonary arteries on the lab bench. The models are made to replicate the human pulmonary artery. The models are made from glass and Lucite. We are also conducting fluid dynamic studies on model valved conduits which are used to surgically correct certain congenital cardiovascular problems. The overall goal of the research program is to obtain a better fundamental understanding of blood flow through the main pulmonary artery, and to design better and longer lasting valved conduits.

IV. Publications

(a) Abstracts and Presentations

1. Woo, Y-R, Williams, F. P., and Yoganathan, A.P., "*In vitro* fluid dynamics characteristics of the Applied Biomedical trileaflet valve prosthesis," *Proceedings of the 3rd International Conference on Mechanics in Medicine and Biology*, pp. 235-236, Compiegne, France, July 1982.

2. Yoganathan, A. P., Harrison, E. C., and Franch, R. H. "Clinical pathologic problems observed with prosthetic heart valves: Possible relationship to fluid dynamics," *Proceedings of the 3rd International Conference on Mechanics in Medicine and Biology*, pp. 201-202, Compiegne, France, July 1982.

3. Yoganathan, A. P. and Franch, R. H., "Hemodynamic characteristics of current prosthetic heart valves," *Proceedings of the Scientific Sessions American Heart Association - Georgia Affiliate*, pp. 21, Pine Mountain, GA, October 1982.

4. Yoganathan, A. P., Franch, R. H., and Harrison, E. C., "Clinical pathologic problems observed with prosthetic heart valves: Possible relationship to fluid dynamics," *Proceedings of the Scientific Sessions American Heart Association - Georgia Affiliate*, pp. 22, Pine Mountain, GA, October 1982.

5. Yoganathan, A. P., "Current status of prosthetic heart valves," *Proceedings of the Division of Organic Coatings and Applied Polymer Science, ACS*, Vol. *48*, pp. 632-638, Seattle, WA, March 1983.

6. Hanle, D. D., Harrison, E. C., Corcoran, W. H., and Yoganathan, A. P., "The measurement of the three dimensional velocity fields downstream of artificial aortic heart valves *in vitro* using laser-Doppler anemometry," *Proceedings of the Joint ASME/ASCE Mechanics Conference*, Houston, TX, June 1983.

7. Yoganathan, A.P., "*In Vitro* Hemodynamics of the St. Jude Bi-leaflet Heart Valve Prosthesis," 3rd International Symposium on the St. Jude Medical Heart Valve, Scottsdale, AZ, November 1982.

8. Stevenson, D. M. and Yoganathan, A. P., "Computer simulation of steady flow through an axisymmetric aortic tissue valve," *Proceedings of the Joint ASME/ASCE Mechanics Conference*, Houston, TX, June 1983.

9. Philpot, E. F., Griffith, L. G., Yoganathan, A. P., and Franch, R. H., "Preliminary *in vitro* flow visualization studies in pulmonary artery models," *Proceedings of the 3rd International Symposium on Flow Visualization*, Ann Arbor, MI, September 1983.

10. Woo, Y-R, Williams, F. P., Yoganathan, A. P., Franch, R. H., and Harrison, E. C., "Steady and pulsatile flow visualization of prosthetic heart valves in current clinical use," *Proceedings of the 3rd International Symposium on Flow Visualization*, Ann Arbor, MI, September 1983.

(b) Manuscripts

1. Yoganathan, A. P., Stevenson, D. M., Williams, F. P., Woo, Y-R., Franch, R. H., and Harrison, E. C., "In vitro fluid dynamic characteristics of the Medtronic-Hall pivoting disc heart valve prosthesis," accepted for publication in Scandinavian Journal of Thoracic and Cardiovascular Surgery, Vol. 16, pp. 235-243, 1982.

2. Yoganathan, A. P., Woo, Y-R., Williams, F. P., Stevenson, D. M., Franch, R. H., and Harrison, E. C., "In vitro fluid dynamic characteristics of Ionescu-Shiley and Carpentier-Edwards tissue bioprostheses," accepted for publication in Artificial Organs, August 1982.

3. Woo, Y-R, Williams, F. P., and Yoganathan, A. P., "In vitro fluid dynamic characteristics of a trileaflet valve prosthesis," accepted for publication in Scandinavian Journal of Thoracic and Cardiovascular Surgery, January 1983.

4. Yoganathan, A. P., Stevenson, D. M., Woo, Y-R, and Strand, D. M., "An on-line method for evaluating the in vitro pulsatile pressure drop and regurgitant characteristics of prosthetic heart valves," accepted for publication in Medical Instrumentation, March 1983.

5. Woo, Y-R, Williams, F. P., and Yoganathan, A. P., "In Vitro fluid dynamic characteristics of the Abiomed trileaflet valve prosthesis," accepted for publication in Journal of Biomechanical Engineering, March 1983.

6. Yoganathan, A. P., Woo, Y-R, Williams, F. P., Chaux, A., Gray, R. J., and Matloff, J. M., "Tilting disc and porcine aortic valve substitutes: in vitro hydrodynamic characteristics," accepted for publication in American Journal of Cardiology, June 1983.

7. Chaux, A., Gray, R. J., Matloff, J. M., and Yoganathan, A. P., "Tilting disc and porcine aortic valve substitutes: in vivo hydrodynamic characteristics," submitted to American Journal of Cardiology, April 1983.

8. Yoganathan, A. P., Chaux, A., Gray, R. J., De Robertis, M., and Matloff, J. M., "Flow Characteristics of the St. Jude prosthetic valve: an in vitro and in vivo study," Artificial Organs, Vol. 6, pp. 288-294, 1982.

9. Stevenson, D. M., and Yoganathan, A. P., "Computer simulation of steady flow through an axisymmetric tissue valve," accepted for publication in Bioengineering Symposium Series, American Institute of Chemical Engineers, November, 1982.

10. Suobank, D. W., Yoganathan, A. P., Harrison, E. C., and Corcoran, W. H., "A quantitative methods for the _in vitro_ study of sounds produced by prosthetic heart valves, Part I: Analytic considerations," accepted for publication in _Medical and Biological Engineering and Computing_, January 1983.

11. Suobank, D. W., Yoganathan, A. P., Harrison, E. C., and Corcoran, W. H., "Part II: An experimental comparative study of the sounds produced by a normal and simulated abnormal Starr-Edwards series 2400 aortic prosthesis," accepted for publication in _Medical and Biological Engineering and Computing_, January 1983.

12. Suobank, D. W., Yoganathan, A. P., Harrison, E. C., and Corcoran, W. H., "Part III: An experimental comparative study of the sounds produced by a normal and simulated abnormal Smeloff aortic prosthesis," accepted for publication in _Medical and Biological Engineering and Computing_, January 1983.